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08/744882

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/744,882	11/08/96	ISNER	J 46963

18M1/0528

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EXAMINER

CANDEL P  
ART UNIT PAPER NUMBER  
1806 4

DATE MAILED: 05/28/97

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

#### OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 30 days month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 1-22 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claim(s) 1-22 are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

### DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-18, drawn to methods of regulating angiogenesis or enhancing blood vessel formation with endothelial cells or modified versions of said cells, classified in Class 424, subclass 93.7.

II. Claim 19, drawn to methods of screening for the presence of ischemic tissue or vascular injury, classified in Class 424, subclass 9.

III. Claim 20, drawn to a composition comprising endothelial cell mitogen and endothelial cell progenitors, classified in Class 424, 93.7 and Class 514, subclass 2.

IV. Claims 21-22, drawn to kits comprising an endothelial cell mitogen or nucleic acid encoding nucleic acid mitogen, classified in Class 514, subclass 2 and 44.

2. Inventions III/IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the products as claimed can be used in a materially different processes such as cells to be used for generating antibodies, mitogens to be used in cell culture or nucleic acids to detect expression.

3. Inventions I and II are different methods of use. These inventions require different ingredients, process steps and endpoints. Therefore they are novel and unobvious in view of each other and are patentably distinct.

4. Inventions III and IV are different products. Endothelial cells, mitogens and nucleic acids are distinct because their structures and modes of action are different. Therefore they are novel and unobvious in view of each other and are patentably distinct.

5. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-IV is not required for any other group from Groups I-IV and Groups I-IV have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

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6. If Invention I is elected, this application contains claims directed to the following patentably distinct species of the claimed invention I: wherein the regulation of angiogenesis comprising administering

- A) a modified endothelial cell or
- B) an unmodified endothelial cell.

These species are distinct because their structures and modes of action are different.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

It is noted that current claims 13-18 do not read on modified endothelial cells.

In addition, applicant is required to select an additional species on Group I. This application contains claims directed to the following patentably distinct species of the claimed invention I: wherein the regulation of angiogenesis comprising

- A) enhancing angiogenesis (claims 1, 3-6, 9, 10, 12-18) or
- B) reducing angiogenesis (claims 1, 2, 7, 8, 11).

These species are distinct because the regulation of angiogenesis differs in therapeutic endpoints and addresses different pathological conditions

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

7. If Invention IV is elected, this application contains claims directed to the following patentably distinct species of the claimed invention IV: wherein the kit comprises:

- A) endothelial cell mitogen or
- B) a nucleic acid encoding an endothelial cell mitogen.

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These species are distinct because their structures and modes of action are different.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 21-22 are generic.

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8. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

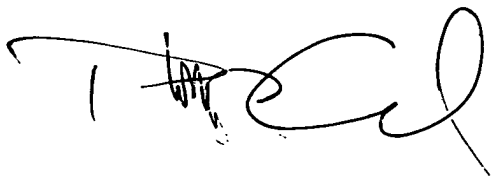
10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

11. Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242 or (703) 305-7939.

12.. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee can be reached on (703) 308-2731. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1800 receptionist whose telephone number is (703) 308-0196.

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Phillip Gambel, Ph.D.  
Patent Examiner  
Group 1800  
May 27, 1997

A handwritten signature in black ink, appearing to be "T. H. C.", written in a cursive style.